

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
27 July 2006 (27.07.2006)

PCT

(10) International Publication Number
WO 2006/078519 A3

(51) International Patent Classification:
A61N 1/365 (2006.01)

(74) Agents: STEFFEY, Charles, E. et al.; Schwegman, Lundberg, Woessner & Kluth, P.A., P.O. Box 2938, Minneapolis, Minnesota 55402 (US).

(21) International Application Number:
PCT/US2006/000963

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(22) International Filing Date: 12 January 2006 (12.01.2006)

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

11/037,308	18 January 2005 (18.01.2005)	US
11/037,723	18 January 2005 (18.01.2005)	US
11/037,309	18 January 2005 (18.01.2005)	US

(71) Applicant (for all designated States except US): CARDIAC PACEMAKERS, INC. [US/US]; 4100 Hamline Avenue North, St. Paul, Minnesota 55112-5798 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): PASTORE, Joseph, M. [US/US]; 9069 Cambridge Road, Woodbury, Minnesota 55125 (US). SALO, Rodney, W. [US/US]; 136 71st Way N.C., Fridley, Minnesota 55432 (US). CARLSON, Gerrard, M. [US/US]; 11653 Nevada Lane, Champlin, Minnesota 55316 (US). KRAMER, Andrew, P. [US/US]; 418 South 6th Street, Stillwater, Minnesota 55082 (US). DING, Jiang [CN/US]; 1237 Countryview Circle, Maplewood, Minnesota 55109 (US). YU, Yinghong [CN/US]; 5953 Keithson Drive, Shoreview, Minnesota 55126 (US).

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARipo (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

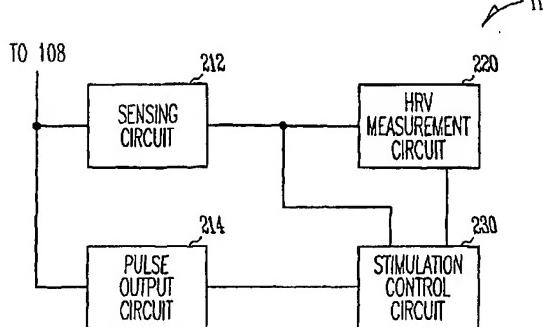
Published:

— with international search report

(88) Date of publication of the international search report:
19 April 2007

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CONTROL OF ELECTRICAL STIMULATION USING HEART RATE VARIABILITY



(57) Abstract: A cardiac rhythm management system modulates the delivery of pacing and/or autonomic neurostimulation pulses based on heart rate variability (HRV). An HRV parameter being a measure of the HRV is produced to indicate a patient's cardiac condition, based on which the delivery of pacing and/or autonomic neurostimulation pulses is started, stopped, adjusted, or optimized. In one embodiment, the HRV parameter is used to evaluate a plurality of parameter values for selecting an approximately optimal parameter value. In another embodiment, the HRV parameter is used to adjust a maximum tracking rate in an atrial tracking pacing mode. In another embodiment, the IIRV parameter is used as a safety check to stop an electrical therapy when it is believed to be potentially harmful to continue the therapy.

WO 2006/078519 A3

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/000963

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/365

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/193066 A1 (CARLSON GERRARD M ET AL) 30 September 2004 (2004-09-30) ----- Y paragraphs [0004], [0007], [0008], [0013], [0040] - [0044]; figures 1,2,7 -----	1-10, 13-16, 20-22 11,12, 17-19
Y	US 2004/260348 A1 (BAKKEN EARL E ET AL) 23 December 2004 (2004-12-23) ----- Y paragraphs [0007], [0029] -----	11,12, 17-19
Y	US 2002/068875 A1 (SCHROEPPEL EDWARD A ET AL) 6 June 2002 (2002-06-06) ----- Y paragraphs [0016], [0017], [0019] ----- -/-	11,12

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the International filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the International search	Date of mailing of the International search report
4 January 2007	24/01/2007
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl. Fax: (+31-70) 340-3016	Authorized officer Schoeffmann, Herbert

INTERNATIONAL SEARCH REPORT

International application No PCT/US2006/000963

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/133247 A1 (STAHHMANN JEFFREY E ET AL) 8 July 2004 (2004-07-08)	41-51, 62-70, 74-76
Y	paragraphs [0020], [0026] - [0028]; figures 1,2 -----	71-73
Y	US 6 144 878 A (SCHROEPPEL EDWARD A [US] ET AL) 7 November 2000 (2000-11-07) the whole document -----	41-51
Y	US 5 540 725 A (BORNZIN GENE A [US] ET AL) 30 July 1996 (1996-07-30) column 3, lines 50-66 -----	41-51
Y	US 6 430 438 B1 (CHEN VICTOR T [US] ET AL) 6 August 2002 (2002-08-06) column 20, line 38 - column 22, line 17; figure 19 -----	71-73

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/000963

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 23–40, 52–61, 77–93
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by therapy
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple Inventions in this international application, as follows:

see additional sheet

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-22

Cardiac rhythm management system in which a heart stimulation parameter is selected in correspondance to a maximum HRV parameter measured for the stimulation parameter optimisation period.

2. claims: 41-51

cardiac rhythm management system that adjusts the MTR based on the HRV parameter.

3. claims: 62-76

cardiac rhythm management system comprising a safety check module to stop execution of a pacing algorithm based on the HRV parameter

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2006/000963

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
US 2004193066	A1	30-09-2004	EP WO US US	1365836 A2 02072196 A2 2002128563 A1 2002128564 A1		03-12-2003 19-09-2002 12-09-2002 12-09-2002
US 2004260348	A1	23-12-2004	CA EP WO	2529783 A1 1641530 A1 2004112897 A1		29-12-2004 05-04-2006 29-12-2004
US 2002068875	A1	06-06-2002		NONE		
US 2004133247	A1	08-07-2004		NONE		
US 6144878	A	07-11-2000		NONE		
US 5540725	A	30-07-1996	DE DE EP JP	69633538 D1 69633538 T2 0753325 A2 9164214 A		11-11-2004 03-03-2005 15-01-1997 24-06-1997
US 6430438	B1	06-08-2002	AU WO US	5276700 A 0071203 A1 2003004551 A1		12-12-2000 30-11-2000 02-01-2003